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Initiation and management of DExcom continuous glucose monitoring in primary care in people living with type 2 diabetes on insulin

Submission date
01/05/2026

Recruitment status
Recruiting

Registration date
05/05/2026

Overall study status
Ongoing

Last Edited
05/05/2026

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
People living with type 2 diabetes need to manage their blood sugar levels carefully to reduce the risk of longterm complications such as heart disease, kidney problems, vision loss, and nerve damage. Many people currently check their blood sugar using fingerprick tests. Continuous Glucose Monitoring (CGM) systems offer an alternative approach by measuring glucose levels continuously through a small sensor worn on the body.
This study aims to evaluate the use of the Dexcom ONE+ Continuous Glucose Monitoring system in routine primary care settings in the United Kingdom and the Republic of Ireland. The Dexcom ONE+ system is already approved for use in the UK and is CE marked. The study will assess whether using CGM helps improve blood sugar control, increases satisfaction for both participants and healthcare professionals, and can be easily integrated into everyday clinical care without disrupting usual practice.

Who can participate?
Adults aged 18 years or older, including people who:
Have been diagnosed with type 2 diabetes for at least three months
Are currently using insulin, either alone or with other diabetes medications
Receive most of their diabetes care in a primary care (general practice) setting
Have a recent HbA1c result greater than 64 mmol/mol

What does the study involve?
Participants will take part in the study for approximately 24 weeks.
At the beginning, study staff will check eligibility during an inperson visit. Participants will first wear a blinded CGM sensor for around 10 days, which collects glucose information that is not visible to them. After this, participants will use an unblinded CGM system for 24 weeks, allowing them to see their glucose readings in real time. Sensors are replaced approximately every 10.5 days.
Participants will be asked to complete several short questionnaires about their diabetes care, general health, and daytoday experiences. Some participants may also be invited to take part in a short interview about their experience of using the CGM system. Interviews may be carried out

remotely or in person and will be audiorecorded, transcribed, and handled confidentially.
A small amount of blood will also be collected during the study for routine testing.

Participants can contact the study doctor or local study team for any questions about the study, to report a studyrelated issue, or to obtain further information. Full contact details are provided in the Participant Information Sheet.

What are the possible benefits and risks of participating?
There may be no direct benefit to participants. However, taking part may help improve understanding of how CGM systems work in everyday primary care settings and contribute to better diabetes care in the future. Participation is voluntary, and individuals may withdraw from the study at any time without it affecting their medical care.

The risks of participation are low. The CGM system is already approved for use in the UK. Possible side effects include mild discomfort, redness, swelling, irritation, itching, bleeding, or infection where the sensor is worn. Blood tests may cause mild discomfort or bruising. There is a small risk to confidentiality, but all personal data will be protected in line with UK data protection laws.

Where is the study run from?
The study is being carried out in primary care (general practice) settings across the United Kingdom and the Republic of Ireland.

When is the study starting and how long is it expected to run for?
March 2026 to June 2027.

Who is funding the study?
The study is funded and sponsored by Dexcom, Inc., a medical device company based in the United States.

Who is the main contact?
Dr Samuel Seidu, sis11@leicester.ac.uk

Contact information

Type(s)
Principal investigator

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Public, Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2026-526711-10-00

Integrated Research Application System (IRAS)
365552

Protocol number
PTL-1000632

Study information

Scientific Title
Single arm study assessing the effect on glycaemic control from baseline to week 24 as measured by HbA1c, with initiation of real-time continuous glucose monitoring (CGM) in a primary care setting, in individuals with type 2 diabetes mellitus (T2DM) on insulin therapy with a baseline HbA1c ≥64 mmol/mol (≥8.0%). Study will include exploratory analysis to assess the effect of CGM compared to standard of care (SoC). Analysis will involve, but not limited to, healthcare resource use, laboratory data, and medication use.

Acronym
INITIATE-CGM

Study objectives
Assess the effect on glycaemic control from baseline to week 24 as measured by HbA1c, with initiation of real-time continuous glucose monitoring (CGM) in a primary care setting, in individuals with type 2 diabetes mellitus (T2DM) on insulin therapy with a baseline Haemoglobin A1c (HbA1c) ≥64 mmol/mol (≥8.0%)

Ethics approval required
Ethics approval required

Ethics approval(s)

approved 02/03/2026, East of Scotland Research Ethics Service (EoSRES) (TAyside medical Science Centre Residency Block Level 3 George Pirie Way Ninewells Hospital and Medical School, Dundee, DD1 9SY, United Kingdom; +44 01382 660111; tay.eosres@nhs.scot), ref: 25/ES/0116

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
This is a two-cohort study in which Cohort 1 follows a single-arm design, while Cohort 2 includes a retrospective matched control arm.

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Type 2 Diabetes Mellitus

Interventions
The study has two cohorts: One will be a single arm with 24 week duration and the other with be a matched arm collecting retrospective data.

Cohort 1: Single Arm (24 Week duration)

Participants will complete the following visits:
- Screening: At this visit, participants will be consented, complete screening procedures and assessment, and begin wearing the blinded CGM for around 10 days. This means they will wear the study device but will not be able to see any values.

- Baseline - Day 0: At this visit, the participant will return their blinded CGM and start using the Real Time (RT)-CGM. They
will receive enough sensors to last until their next visit.

- Follow-up -Day 28/ Week 4: At this time point, the investigator will review the participants RT-CGM, and if the
participants values are trending well, the investigator will mark the visit complete and participant will not be contacted. If the RT-CGM values require action (eg. change in medications, etc), the investigator will call or schedule the
participant for a visit. This mean the participant will be contacted.

-Follow-up - Day 84/ Week 12: The participant will return to the study centre and download the data from the RT-CGM, complete questionnaires, and labs. Sponsor may reach sites to schedule a meet with the participant to conduct
interview or complete in person.

- Final - Day 168/ Week 24: The participant will return to the study centre and download the data from the RT-CGM,
complete questionnaires, and labs. Sponsor may reach sites to schedule a meet with the participant to conduct
interview or complete in person.

Cohort 2: Matched Arm
Enrollment in Cohort 1 will be complete and all participants will complete all visits before enrolling into cohort 2.

Participants will complete the following visits:
- Screening: At this visit the participant will be consented, and begin eligibility criteria. The participant is consenting to have their data retrospectively reviewed and retrieved at the time of screening. For this cohort, assessment will occur
at the start of the data collection period, defined as a 24-week retrospective interval. This 24-week period may occur at any time within the last 12 months. Eligibility will be determined based on data available at the beginning of the
retrospective 24-week data collection window. Upon completion of this visit, the participant will have fulfilled all study
requirements. No further visits are anticipated.

Participants in both cohorts will be assessed according to the same eligibility criteria and the single arm will have a
few more.

Intervention Type
Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Dexcom ONE + CGM System

Primary outcome(s)
1. HbA1c level measured using data collected from CGM (cohort 1) compared with retrospective data from local laboratory testing (cohort 2) at continuous versus retrospective time points between baseline and week 24

Key secondary outcome(s))
1. HbA1c level measured using data collected from CGM (cohort 1) compared with retrospective data from local laboratory testing (cohort 2) at continuous versus retrospective time points between baseline and week 12

2. HbA1c levels: ≥69 mmol/mol (≥8.5%), ≥75 mmol/mol (≥9.0%), ≥80 mmol/mol (≥9.5%), ≥86 mmol/mol (≥10.0%), stratified by baseline HbA1c measured using data collected from CGM

(cohort 1) compared with retrospective data from local laboratory testing (cohort 2) at continuous versus retrospective time points between baseline and weeks 12 and 24

3. HbA1c thresholds, defined as the percent participants reaching HbA1c ≤53 mmol/mol (≤7.0%), percent participants reaching target HbA1c of ≤58 mmol/mol (≤7.5%), percent participants decreasing HbA1c by ≥0.5%, percent participants reaching HbA1c 7% and/or decreasing by 0.5% measured using data collected from CGM (cohort 1) compared with retrospective data from local laboratory testing (cohort 2) at weeks 12 and 24

4. CGM-derived metrics measured using CGM-determined percent of time in range (TIR) (3.9-10.0 mmol/L), CGM-determined percent of time in tight range (TITR) (3.9-7.8 mmol/L), CGM-determined glucose management indicator (GMI), CGM-determined mean glucose, CGM-determined glucose variability (coefficient of variation (CV) and standard deviation (SD)), CGM-determined percent of time above range (TAR) level 1 (>10.0 mmol/L and ≤13.9 mmol/L), CGM-determined percent time >10.0 mmol/L, CGM-determined percent TAR level 2 (>13.9 mmol/L), CGM-determined percent time >16.7 mmol/L, CGM-determined time below range (TBR) level 1 (<3.9 mmol/L and ≥3.0 mmol/L), CGM-determined percent <3.9 mmol/L, CGM-determined percent TBR level 2 (<3.0 mmol/L), CGM- determined low glucose episodes (defined as glucose values detected by CGM of <3.0 mmol/L for at least 15 minutes, preceded by minimum of 30 minutes of glucose values >3.0 mmol/L from baseline at baseline to weeks 12 and 24 (over 24 hours and daytime and nighttime individually)

5. CGM-derived thresholds measured using percent participants increasing TIR by ≥5%, percent participants with TIR ≥70% at weeks 12 and 24

6. Primary care workflow and resource use measured using change in primary care resource utilisation from baseline to scheduled visits: the number of primary care visits (overall and for diabetes management individually); number of referrals to secondary/specialist care; change in medication and consumables (e.g. test strips), baseline data will be retrospectively collected from the previous 6 months at time of screening, time required for HCP to set up participants with CGM at initiation, percent of participants who need additional support from primary care HCP following initiation to set up and to be started on CGM at the previous 6 months at time of screening and from baseline to scheduled visits

7. Combined glycaemic control and primary care resource use outcomes measured using percent participants at week 24 decreasing HbA1c by ≥0.5% AND attended ≤ same number of primary care visits during the intervention as 6 months prior (collected retrospectively), percent participants at week 24 increasing TIR ≥5% AND attended ≤ same number of primary visits during the intervention as 6 months prior at week 24 and at 6 months prior (collected retrospectively)

8. Body weight measured using standard measurements and retrospective data at baseline, 12 and 24 weeks

9. Body mass index (BMI) measured using standard measurements and retrospective data at baseline, 12 and 24 weeks

10. Daily insulin dose/kg body weight (bolus and basal) measured using change in daily insulin dose/kg body weight (bolus and basal) at baseline to 12 and 24 weeks

11. Blood lipids (CHOL, TRG, HDL, LDL) measured using change in blood lipids (CHOL, TRG, HDL, LDL) at baseline to 12 and 24 weeks

12. Estimated cardiovascular disease risk measured using change in estimated cardiovascular disease risk at baseline to 12 and 24 weeks

13. Total medication use (adding or removing medications, dose changes) measured using data from medical records at baseline, 12 and 24 weeks

14. Secondary care healthcare resource utilisation (number of hospitalizations (total and split by reason), outpatient visits, and tests measured using data from medical records at 24 weeks prior to screening (historical data collected retrospectively) to 24 weeks.

15. Status and changes in psychosocial and behavioural aspects of diabetes measured using patient-reported outcome measures and in participant qualitative interviews at study completion

Completion date
01/06/2027

Eligibility

Key inclusion criteria
1. Age at least 18 years.
2. Clinical diagnosis of Type 2 diabetes on insulin for a minimum of 3 months duration confirmed via medical records/source documentation by a qualified individual to make a medical diagnosis.
3. Diabetes care predominately managed in primary care.
Note: Secondary care diabetes management will not be exclusionary if the majority of diabetes care is managed in the primary care setting.
4. HbA1c ≥64 mmol/mol (≥8.0%)
Note: By local lab at screening or within 28 days of screening by local lab or POC. Additionally, cohort 2 participants must have at minimum, two HbA1c lab results available.
5. Stable diabetes, cardio-metabolic (e.g., lipid lowering and hypertensive medications) and anti-obesity medication regimen (medication classes) and dose (equivalent dose if diabetes/cardio-metabolic/anti-obesity- specific medication has been changed within same medication class) for 3 months prior to enrolment.
Note: Changes ≤ 10% in total daily doses of insulin in the 3 months prior to screening are considered stable.
6. Participant capable of becoming pregnant must have a negative urine pregnancy test at time of screening and do not plan pregnancy.
Note: Participants are classified as non-childbearing potential due to menopause (with at least one year since last menses), a medical condition or medical surgery confirmed by the investigator.
7. Investigator believes that the participant has the cognitive capacity to provide informed consent

Cohort 1 Only:
8. Can successfully and safely use CGM and is capable and willing to follow study procedures.
Note: This includes considering the potential impact of medical conditions known to be present including cardiovascular, liver, kidney disease, thyroid disease, adrenal disease, malignancies, vision difficulties, active proliferative retinopathy, skin or skin allergy condition, Human Immunodeficiency Virus (HIV), Hepatitis B or Hepatitis C infections; haemophilia; and other medical conditions; psychiatric conditions including eating disorders; drug or alcohol abuse

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Diagnosis of type 1 diabetes.
2. Any surgical procedure for weight loss within the year prior to enrolment or plans for undergoing such bariatric surgery during the study.
3. Concomitant disease or condition that in the opinion of the investigator may compromise participant safety, including but not limited to; cystic fibrosis, severe mental illness, a diagnosed or suspected eating disorder or any uncontrolled long term medical condition that would interfere with study related tasks or visits.
4. Use of medications known to exacerbate hyperglycaemia (current or for more than 14 days in the past 3 months), corticosteroids (oral and injectable) or certain psychotropics (antipsychotics, e.g., clozapine, olanzapine, risperidone, and quetiapine).
5. Breastfeeding.
6. Anticipated acute uses of glucocorticoids (oral, injectable, or IV), that will affect glycaemic control and impact HbA1c.
7. Presence of a haemoglobinopathy or other condition that is expected to affect the measurement of HbA1c in the judgment of the investigator.
8. The participant, immediate family member(s), and/or person(s) living within the household work for Dexcom, Medtronic, Ypsomed, SiBionics, Glysens Inc., Abbott Laboratories, Roche, Senseonics, Waveform, Ascensia Diabetes Care, Yuwell, i-SENS, Bionime, POCTech, or Insulet and any other diabetes company; immediate relation to study staff.
9. Current participation in another interventional study protocol or prior participation in an interventional study protocol in which the participant received active drug within the 90 days prior to screening.
Note: Participants will not be excluded if enrolled in another observational trial, wherein the participant is in the follow-up phase and no tests/procedures impacting the participant's health are required. Participants participating in studies using only approved medications (that are not specifically excluded) or devices may qualify for this study.
10. Use of personal real-time or intermittent scanned (Flash) CGM, or use of a glucose biosensor, 6months prior to screening.
Note: Previous wear of a professional CGM will not be exclusionary.
11. End stage renal disease currently managed by dialysis or anticipating initiating dialysis during

the next 6 months, OR eGFR <15.
Note: Baseline blinded CGM data collection can be initiated prior to the lab result being available but lab result must be available prior to initiation to verify eligibility.

Cohort 1 Only
12. Thyroid stimulating hormone (TSH) outside the local laboratory's reference range (above or below).
Note: Baseline blinded CGM data collection can be initiated prior to the lab result being available but lab result must be available to verify eligibility before baseline visit.
13. Known severe allergy to medical grade adhesives or a serious skin condition that precludes use of the CGM.
14. Current or planned use of hydroxyurea.

Date of first enrolment
12/03/2026

Date of final enrolment
31/01/2027

Locations

Countries of recruitment
United Kingdom

England

Ireland

Study participating centre
Northenden Group Practice
489 Palatine Road
Manchester
England
M22 4DH

Study participating centre
Hockley Farm Medical Practice
39 Hockley Farm Rd
Leicester
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LE3 1HN

Study participating centre
Manchester Integrative Medical Practice
20 Monton Street

Manchester
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M14 4GP

Study participating centre
Preston Hill Surgery
121 Preston Hill
Harrow
England
HA3 9SN

Study participating centre
Ashton Medical Group LTD
Chapel Street
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OL6 6EW

Study participating centre
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Alexandra Road, Shipley, West Yorkshire
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Sponsor information

Organisation
Dexcom (United States)

ROR
https://ror.org/03ra42c27

Funder(s)

Funder type

Funder Name
Dexcom

Alternative Name(s)
Dexcom, Inc.

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available